April 2, 2019

Hon. Paul W. Grimm
United States District Judge
6500 Cherrywood Lane
Greenbelt, MD 20770

RE: American Academy of Pediatrics, et al., v. FDA (No. 8:18-cv-883-PWG)

Dear Judge Grimm,

Plaintiffs write to request reconsideration of the Court's March 26, 2019 Letter Order (Doc. No. 62) or, in the alternative, a status conference to discuss the timetable on which FDA expects to issue a final revised Guidance. Plaintiffs respectfully submit that the possibility of future regulatory changes does not warrant denying the parties' cross-motions, and that the purposes of Federal Rule of Civil Procedure 1 would be best served by resolving the motions now, rather than deferring them.

Plaintiffs share the Court's concern for the efficient resolution of this matter, along with the goal of avoiding duplicative proceedings. While Plaintiffs appreciate the Court's expectation that declining to resolve Plaintiffs' challenge to the operative Guidance is the more efficient course of action, there is substantial reason to think that ruling on the cross-motions would be equally efficient if not more so.

The FDA has begun a rulemaking process on an issue that, by its own assessment, involves an "epidemic-level" crisis. Gottlieb Stmt. at 2 (ECF 59-2). It has informed the public what the final output might look like, but it has also (as it must) invited public comment and will not be able to finalize its forthcoming policy until it has analyzed and responded to those comments. If FDA has the benefit of a ruling on its existing Guidance, its ability to issue a legally sustainable replacement—thus obviating or at least simplifying challenges to that replacement—will increase significantly. This is true whichever way the Court rules in this case: if the Court strikes down the operative Guidance, FDA would know the legal rules it must follow to make its forthcoming guidance valid; if the existing Guidance is ultimately found to be lawful, many of the arguments Plaintiffs raised against it might be pointless to bring against the replacement guidance.

Thus, deciding the motions that are already fully briefed and ripe for resolution would clarify the basic foundational principles that the prospective guidance must satisfy, either allowing FDA to

avoid legal pitfalls ahead of time or making it clear that FDA's underlying view of the scope of its discretion is correct. Ruling on the existing motions would expedite matters for this Court or any other court that has to consider the legality of the hypothetical new guidance.

Moreover, the legality of the 2017 Guidance will need to be litigated even if the Court declines to rule on the parties' cross-motions. When agency action is invalidated, the typical result is the restoration of the status quo before that action. Under that default, if the hypothetical future guidance is challenged and vacated, the 2017 Guidance would be expected to go back into effect. To avoid that outcome, Plaintiffs would need to address the legality not only of the replacement guidance but the 2017 Guidance as well, and FDA would need to defend both actions. From the perspective of the parties, therefore, deferring ruling now does not create efficiencies; if anything, it risks increasing the burdens if FDA does issue a replacement.

With the efficiency calculus roughly in equipoise, the other goals of the Federal Rules of Civil Procedure—that determinations be "just" and "speedy," Fed. R. Civ. P. 1—take on greater significance. Both of these concerns weigh heavily in favor of deciding the motions now.

First, the Rules' mandate of a speedy determination plainly counsels in favor of resolution. Plaintiffs filed their suit in March 2018, and promptly moved for summary judgment. Now, more than a year later, the suit is being put on indefinite hold while FDA undertakes notice and comment prior to the issuance of new guidance. The administrative process, of course, is not known for its speed. FDA took four months to issue a proposed Draft Guidance after first informing the Court that it was considering changes, and is undertaking the notice and comment process only now. The comment period will undoubtedly attract numerous comments from industry representatives, public health advocates such as Plaintiffs, and interested individuals. The agency must, among other things, evaluate and respond to those comments for its ultimate rule to be sustainable.[1] Moreover, it must act with the knowledge that any action it takes will likely be challenged in court, whether by Plaintiffs here or by the notoriously litigious tobacco industry (whose members and representatives filed at least nine challenges to the Deeming Rule in at least six jurisdictions).[2] And FDA is in the midst of a leadership change that will

[1] *See, e.g.*, *NorAm Gas Transmission Co. v. FERC*, 148 F.3d 1158, 1165 (D.C. Cir. 1998) ("It most emphatically remains the duty of [federal courts] to ensure that an agency engage the arguments raised before it … .") (internal quotation marks omitted); *Nat'l Women's Law Ctr. v. Office of Mgmt. & Budget*, --- F. Supp. 3d ----, 2019 WL 1025867, at *17 (D.D.C. Mar. 4, 2019) ("Without explaining why, an agency cannot rely on some comments while ignoring comments advocating a different position.").

[2] *See Nicopure Labs, LLC v. FDA*, No. 16-cv-878 (D.D.C.); *Lost Art Liquids, LLC v. FDA*, No. 16-cv-3468 (C.D. Cal.); *Cyclops Vapor 2, LLC v. FDA*, No. 16-cv-556 (M.D. Ala.); *Faircloth v. FDA*, No. 16-cv-5267 (S.D. W. Va.); *Sanchez Icaza & Global Premium Cigars v. FDA*, No. 16-cv-21967 (S.D. Fla.); *Right to be Smoke-Free Coalition v. FDA*, No. 16-cv-1210 (D.D.C.); *Cigar*

undoubtedly delay any action.[3] There is thus no reason to expect that a final Guidance is imminent, and substantial reason to doubt that it will issue this year.

Second, and perhaps most importantly, this case involves an ongoing crisis of e-cigarette usage by young people that, by Commissioner Gottlieb's own admission, was fostered in part by the Guidance that Plaintiffs challenge. *See* ECF 61 at 3; ECF 61-1 at 3. That Guidance remains in place today—and, as a result, thousands of addictive and harmful products, with great appeal to youth, continue to be sold without premarket review, contrary to Congress's mandate. Forgoing a decision on the lawfulness of that Guidance will result in the continued availability to youth of addictive tobacco products throughout the pendency of any delay, as well as the continued impairment of physicians' and public health organizations' ability to respond to the emerging crisis. Even if the Court rejects Plaintiffs' claims, FDA will have the benefit of being able to shape its future policy within a clearer legal framework. In either case, the Rules' mandate of a just determination counsel against immunizing the Guidance from challenge while it remains in force.

There is nothing unusual about resolving challenges to operative agency rules at the same time that the agency is considering replacing them. Courts routinely decide cases where the existing rule or policy is much closer to obsolescence than is the guidance here. In *Becerra v. U.S. Department of Interior*, 276 F. Supp. 3d 953 (N.D. Cal. 2017), for example, the court granted plaintiffs' motion for summary judgment and declared the stay of an earlier rule unlawful even though the agency had *already* repealed the original rule in a final rule set to take effect a week after the court's ruling. *See id.* at 957, 959-61.[4]

This is, perhaps, why neither party requested that the Court deny or stay the pending motions. FDA did not suggest that FDA's Draft Guidance mooted the pending motions, rendered them unripe, or otherwise made them inappropriate for resolution. There is no dispute that the Court has the authority to resolve the pending motions notwithstanding the possibility that the regulatory landscape will change in the near future. The only question is whether doing so would

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Ass'n of Am. v. FDA, No. 16-cv-1460 (D.D.C.); *En Fuego Tobacco Shop LLC v. FDA*, 18-cv-28 (E.D. Tex.); *Moose Jooce v. FDA*, No. 18-cv-203 (D.D.C.).

[3] *See* Laurie McGinley et al., *FDA Commissioner Gottlieb, Who Raised Alarms About Teen Vaping, Resigns,* Wash. Post, Mar. 5, 2019, https://www.washingtonpost.com/health/2019/03/05/fda-commissioner-gottlieb-who-raised-alarms-about-teen-vaping-resigns/?utm_term=.773134d73f3c.

[4] *See also, e.g.*, *Chamber of Commerce v. U.S. Dep't of Labor*, 885 F.3d 360 (5th Cir. 2018) (vacating rule even though agency had already stayed the rule and invited comment on replacing it); *Natural Resources Defense Council v. U.S. Dep't of Energy*, --- F. Supp. 3d ----, 2019 WL 858748 (S.D.N.Y. Feb. 22, 2019) (vacating stay even though agency had already lifted the stay and stated that it was "likely" to take related action).

secure a "*just*, *speedy*, and inexpensive determination." Fed. R. Civ. P. 1 (emphasis added). Declining to resolve Plaintiffs' claims would not be just or speedy, and may not be less expensive; indeed, it would not be a determination at all.

To the extent the Court is concerned about the impact on regulated entities of invalidating the Guidance when a new policy could be issued in the near future, remand without vacatur is a standard judicial tool for avoiding disruption.[5] As Plaintiffs noted in their summary judgment reply, the Court has equitable power to "tailor its remedy to the occasion." ECF No. 39 at 40 n.14 (quoting *NAACP v. Sec'y of HUD*, 817 F.2d 149, 160 (1st Cir. 1987)). If FDA is truly on the verge of issuing new guidance, the Court can stay its mandate or remand without vacatur, allowing FDA some time to finalize a lawful replacement for the Guidance—but making clear that failing to do so promptly will result in vacatur of the operative Guidance.

Alternatively, Plaintiffs respectfully request a status conference to discuss FDA's timeline for finalizing the Draft Guidance. If FDA does not expect that it will be able to finalize the Guidance promptly, denying the motions would delay resolution of this case and prolong what is conceded to be a public health crisis without achieving any offsetting benefit. As it is, neither Plaintiffs nor the Court have any way of knowing whether FDA anticipates issuing revised final guidance in weeks, months, or next year. While the status reports ordered by the Court could help in this regard, it is unclear how long FDA can simply report that it is reviewing comments and preparing the forthcoming guidance before the Court would consider taking the denied motions back up. A status conference would allow the parties and the Court to resolve questions on this front and allow the parties to be heard on a substantial question that has not been the subject of briefing.

Respectfully submitted,

/s/
Jeffrey B. Dubner

[5] *See, e.g.*, *Becerra*, 276 F. Supp. 3d at 966-97 (remanding without vacatur where repeal of original rule was set to take effect in less than a week); *Md. Native Plant Soc'y v. U.S. Army Corps of Eng'rs*, 332 F. Supp. 2d 845, 862-63 (D. Md. 2004) (remanding without vacatur).